AUG 1 6 2004

K033918 page 1 of 4

510(k) Summary

This 510(k) Summary of Safety and Effectiveness for the **EBI LactoSorb® Graft Containment System** is provided as required per Section 513(I)(3) of the Food, Drug and Cosmetic Act.

1. **Submitter:** Jon Caparotta, RAC
Manager Regulatory Affairs
EBI, L.P.
100 Interpace Parkway
Parsippany, NJ 07054

Contact Person: Frederic Testa, RAC
Telephone: 973-299-9300, ext.2208
Fax: 973-257-0232

Date prepared: August 9, 2004

2. **Proprietary Name:** **EBI LactoSorb® Graft Containment System**
Common Name: Plate, Bone
Classification Name/Code: HRS

3. **Predicate or legally marketed devices that are substantially equivalent:**

- MacroPore OS Trauma System, K021164 by MacroPore, Inc.
- MacroPore OS Protective Sheet, K994158 by MacroPore, Inc.
- Synthes Resorbable Meshes & Sheets, K003788 by Synthes (USA).
- Lorenz LactoSorb Panels and Fasteners K011139 by Biomet, Inc.
- Biomet LactoSorb Panels and Fasteners K984390 by Biomet, Inc.
- LactoSorb Trauma Plating System, K992355 by Biomet, Inc.

4. **Device Description:** The LactoSorb® Graft Containment System, a resorbable graft containment system, is made from LactoSorb, which is composed of bioresorbable, and biocompatible polymers that have been used in surgical procedures for years. LactoSorb resorbable copolymer is derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs *in vivo* by hydrolysis to lactic and glycolic acids, which are then metabolized by the body. The LactoSorb material has been found in animal and clinical studies to be biocompatible in both soft tissue and bone tissue. Preclinical and clinical studies have proven the safety and effectiveness of these devices. They have been approved to be used in trauma and reconstructive procedures in the midface and craniofacial skeleton, and for maintaining the position of bony fragments or morselized bone graft in iliac crest autograft procedures.

The LactoSorb mesh panel/sheet is provided in sizes of 25 mm x 25 mm to 100 mm x 100 mm and in other shapes and sizes as needed for particular surgical procedures. The thickness of the mesh panel/sheet ranges from 0.50 mm to 2.0 mm, according to the region to be treated, and are provided with and without macro porous holes. The borders of the mesh panel/sheet may be aligned with holes to attach suture material.

The LactoSorb mesh panel/sheet can be made malleable and shaped to conform to the specific anatomy. The mesh panel/sheet can be heated to a malleable state using a hot sterile/saline water bath (K011237) or a sterile LactoSorb® Heat Pack (K941245). The mesh panel/sheet can be cut into various shapes and sizes. EBI heat contouring pen can also be used for both cutting and in-situ shaping of the mesh panel/sheet. The mesh panel/sheet can be used either alone or in conjunction with fixation devices such as resorbable sutures, screws and rivets to keep the device

K033918 page 4 of 4

in place. Various manual instruments are available to implant the LactoSorb® Graft Containment System.

5. **Intended Use:** The LactoSorb® Graft Containment System is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The LactoSorb® Graft Containment System is also indicated for cement restriction in total joint arthroplasty procedures. Only when used in conjunction with traditional rigid fixation, the LactoSorb® Graft Containment System is intended to maintain the relative position of weak bony tissue in trauma and reconstructive orthopedic procedures involving: long bones, flat bones, short bones, irregular bones, appendicular skeleton and thorax. When used alone (without traditional rigid fixation), the LactoSorb® Graft Containment System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving: tumor resections where bone strength has not been compromised and iliac crest harvests. This device is not intended for use in the spine. The device is not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

6. **Comparison to the Predicate Device:**

   There are no significant differences between the EBI LactoSorb® Graft Containment System and the following predicate devices:

   - MacroPore OS Trauma System, K021164 by MacroPore, Inc.
   - MacroPore OS Protective Sheet, K994158 by MacroPore, Inc.
   - Synthes Resorbable Meshes & Sheets, K003788 by Synthes (USA).
   - Lorenz LactoSorb Panels and Fasteners K011139 by Biomet, Inc.
   - Biomet LactoSorb Panels and Fasteners K984390 by Biomet, Inc.
   - LactoSorb Trauma Plating System, K992355 by Biomet, Inc.

   The LactoSorb® Graft Containment System is substantially equivalent to the predicate devices in regards to intended use, material and function.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355.)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Mr. Jon Caparotta, RAC
Manager, Regulatory Affairs
EBI, L.P.
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K033918
Trade Name: EBI LactoSorb® Graft Containment System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: May 27, 2004
Received: May 28, 2004

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

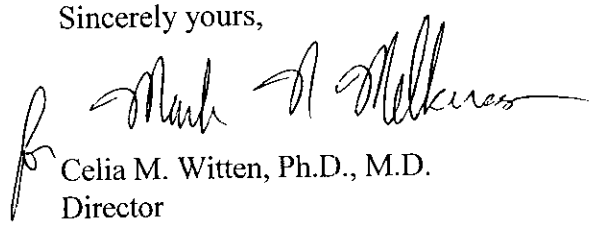
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033918

Device Name: **EBI LactoSorb® Graft Containment System**

Indications For Use:

The LactoSorb® Graft Containment System is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The LactoSorb® Graft Containment System is also indicated for cement restriction in total joint arthroplasty procedures. Only when used in conjunction with traditional rigid fixation, the LactoSorb® Graft Containment System is intended to maintain the relative position of weak bony tissue in trauma and reconstructive orthopedic procedures involving: long bones, flat bones, short bones, irregular bones, appendicular skeleton, thorax and ribs. When used alone (without traditional rigid fixation), the LactoSorb® Graft Containment System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopedic procedures involving: tumor resections where bone strength has not been compromised and iliac crest harvests. The device is not intended for use in the spine. The device is not intended for load bearing applications unless used in conjunction with traditional rigid fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033918